DEC 0 6 2001

Appendix E: Summary of Safety and Effectiveness Data

K013047

I. General Information

Company :	Fotona d.d. Stegne 7, 1210 Ljubljana SLOVENIA
Contact Person :	Mojca Valjavec
Preparation Date :	05-09-01
Device Trade Names :	Fotona Dualis^{XP} Nd:YAG Laser System Fotona Dualis^{VP} Nd:YAG Laser System Fotona Twinlight Nd:YAG Laser System
Common Name :	Nd:YAG Pulsed Surgical Laser System
Classification Name :	Instrument, Surgical, Powered, Laser 79-GEX 21 CFR 878-48

II. Description

The family of Fotona Dualis systems is based on the Nd:YAG laser technology. Within the systems, an optical cavity contains the Nd:YAG crystal, which is activated by means of the use of flashlamps. After the cavity, a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapeutic and aiming beams are guided down an optical fiber delivery system to a focusing handpiece. The laser is used in non-contact mode.

II. Intended Use

The family of Fotona DUALIS Nd:YAG laser systems is indicated for use in surgical and aesthetic applications requiring selective photothermolysis of target chromophores in soft tissue in general and plastic surgery and dermatology. In addition, the family is indicated to effect stable long-term, or permanent hair reduction in Fitzpatrick skin types I - VI through selective targeting of melanin in hair follicles (where permanent hair reduction is defined as a long-term stable reduction in number of hairs regrowing after a treatment regimen).

III. Summary of Substantial Equivalence

The family of Fotona DUALIS lasers shares the same general indications for use, and therefore is substantially equivalent to the currently marketed Laserscope Lyra (K010834) and to Altus Medical Aesthetic Nd:YAG Laser (K003202).

Technologically, the predicate devices have similar characteristics to the DUALIS lasers. All systems comprising a flashlamp pumped Nd:YAG laser rod generating light at a wavelength of 1064 nm, which is subsequently delivered to the patient via an optical fiber delivery system and focusing handpiece.

All lasers utilize class I aiming beams which pose no hazard to the user.

All systems are microprocessor controlled devices. The microprocessor control regulates normal operation, permits parameter selection and avoids hazard incidence.

All systems utilize an internal closed loop water-air heat exchanger circuit for optimal thermal control of the laser cavity.

The risk and benefits for the DUALIS family are comparable to the predicate devices when used for similar clinical applications.

It is therefore believed that there are no new questions of Safety or Effectiveness raised by the introduction of the DUALIS family.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2001

Mojca Valjavec, Dipl. Eng.
Laser Division
Fotona d.d.
Stegne 7
1210 Ljubljana
Slovenia

Re: K013047
Trade Name: Fotona DUALIS Nd: YAG Laser System
Regulation Number: 878.4810
Regulation Name: Laser Surgical Instrument
Regulatory Class: II
Product Code: GEX
Dated: September 6, 2001
Received: September 10, 2001

Dear Ms. Valjavec:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX F

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013047

Device Name: **Family of Fotona DUALIS Nd:YAG Laser Systems and Accessories**

Indications For Use:

The family of Fotona DUALIS Nd:YAG laser systems is indicated for use in surgical and aesthetic applications requiring selective photothermolysis of target chromophores in soft tissue in the medical specialities of general and plastic surgery and dermatology:

- To effect stable long-term, or permanent, hair reduction in skin types I - VI through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.
- For removal of unwanted hair.
- For coagulation and hemostasis of vascular lesions.
- For incision/excision of soft body tissue in dermatology
- For soft tissue general surgery applications - skin incision; tissue dissection; complete or partial resection of internal organs, tumors, lesions; tissue ablation; vessel coagulation

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

Susan Walker, M

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013047